Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

10 August 2018

English only

2018 Meeting
Geneva, 4-7 December 2018

Meeting of Experts on Institutional strengthening of the Convention
Geneva, 16 August 2018
Item 4 of the provisional agenda
Consideration of the full range of approaches and options to further strengthen the Convention and its functioning through possible additional legal measures or other measures in the framework of the Convention

Institutional Strengthening of the BWC

Submitted by the United States of America

1. The 2017 Meeting of BWC States Parties agreed that an expert group (MX5) on institutional strengthening would be included in the intersessional work program for 2018-2020. The agreed mandate for that group reflects the desire to have a broad-ranging discussion. It states:

> *"...consideration of the full range of approaches and options to further strengthen the Convention and its functioning through possible additional legal measures or other measures in the framework of the Convention..."*

2. As a starting point, it is important to have a clear idea of State Parties' concerns and objectives: that is, how do they view the biological weapons threat, and what aspects of the Convention's institutions do they believe need to be strengthened? It is also important to consider what steps have already been taken to strengthen the Convention institutionally, what additional approaches have been suggested, and what issues or problems these approaches may present.

What are U.S. concerns about the threat of biological weapons?

3. The United States considers the BWC to be the key instrument for strengthening international security against the threat of biological weapons. We believe that the experiences with BWC implementation in the four decades since the BWC came into force, and the developments that have occurred since then, warrant a concerted effort to strengthen the BWC regime and keep it relevant in the face of evolving threats. It is fundamental that efforts to strengthen the Convention should enhance international security by reducing the risk of biological weapons development, retention, acquisition, or use, and

that this should take into account the current and likely future nature of the threat. The U.S. perceives three broad categories of BW threats:

- Large-scale BW threats: We are concerned that some countries' past biological weapons programs may continue to exist and new forms of biological weapons may be created through misuse of advances in science and technology. While the threat of deliberately caused disease outbreaks among people has received greatest attention, the United States is also concerned about potential attacks on crops and livestock.
- Small-scale/deniable use: The biological weapons threat has evolved since the BWC came into force in 1975. This fact is in part due to scientific and technological advances, but also is influenced by changes in the nature of international conflict. State and non-State BW programs could be particularly hard to detect if their aim is for small-scale, deniable use. Such a program could pose a grave threat to U.S. or international security, but might require only small-scale production equipment and very little in the way of delivery systems, especially if targeted against civilian populations or employing a highly contagious or virulent pathogen. In fact, the very success of the BWC as a normative instrument may have served to steer some nations toward this model of employment, which might permit them to avoid the consequences of being identified as perpetrators of a BW attack.
- Non-State Actors: The United States assesses that the most likely near-term threat of biological weapons use is by a terrorist or insurgent group. Such groups have repeatedly demonstrated the intent to acquire and use biological weapons, and their lack of success to date is no guarantee that they might not eventually succeed. In these cases, the challenge of detecting clandestine offensive BW activity prior to use is likely to be even greater. The evolving threat from the use of biological weapons by such actors can be best addressed through the requirements for both effective controls on transfers in Article III and for a range of effective national measures taken under Article IV. Any effort to strengthen the Convention would need to assign particular priority to improving the adoption, implementation, and enforcement of those national measures required by the BWC.

How have technical advances and other developments changed the situation since 2001?

4. Since 2001, dramatic changes have taken place that impact the implementation of and the monitoring of compliance with the Biological Weapons Convention. Very rapid advances in science and technology have expanded tremendously the ability to manipulate biological organisms and led to the development of whole new industries based on biotechnology with capabilities not even imagined in 2001.

5. Relevant research advances include:

- manipulation of genetic material and microorganisms in order to understand the pathogenicity of specific microbes;
- applications of synthetic biology intended to "redesign" organisms with desired characteristics and functionalities that are generally not found in nature;
- developments in DNA sequencing that drastically reduce the time and cost, making this process increasingly widely available;

- advances in high-capacity computing and information technology which, again, have played a major role in increasing understanding of pathogenicity; and
- discoveries in the fields of immunology and molecular biology that have had an enormous impact on the identification of candidate vaccines against diseases that, until a few years ago, seemed uncontrollable.

6. While the United States is a strong proponent of the biotechnology transformation and recognizes that it is fundamental to global health and prosperity, it is important to ensure that the advances that are accelerating at an unprecedented rate across the globe unfold in a safe and secure manner.

7. Complicating the situation is the fact that many of the traditional "signatures" that characterized a biological weapons program before 2000 are no longer valid. Use of microorganisms for legitimate purposes has proliferated. While some may still use fixed fermentation systems, in many facilities, disposable equipment is used, making it impossible to detect traces of illicit activity. Improved processes for cultivating microorganisms and the changing nature of warfare (see below) means that mass production and stockpiling of weaponized biological material is no longer necessary or desirable. The proliferation of biotechnology in the global economy has led to diffusion of technology, ideas and skills throughout the world. As a result, biotechnological developments may proceed in unconventional settings outside of universities and major research institutions.

8. Furthermore, the nature of armed conflict has changed since 1975, when the preoccupation of planners was the threat of a large-scale conflict involving hundreds of thousands of heavily armed combatants and encompassing vast areas. Biological weapons programs in that era involved large weapons programs, sizeable quantities of agent, and numerous facilities. While that scenario is still plausible in some circumstances, armed conflicts in 2018 are playing out on a much smaller scale in terms of both combatants and territory. A number are essentially civil wars or insurgencies that pit government forces against an armed opposition that is receiving outside assistance. In this context, biological weapons programs are likely to be much smaller in scale.

9. Over the period since 2001, non-State actors such as ISIL have emerged as a serious threat to national and international security. The dual-use nature of knowledge and expertise, combined with the diffusion of information and decreasing costs, have enabled smaller groups and even individuals to try to use biology for their own malevolent purposes. The interest of some non-State actors in biological weapons is very disturbing.

10. Thus, developments in science and technology, as well as in the nature of armed conflict, have complicated even further the already very difficult challenge of ensuring that biological weapons are never again used.

How have State Parties proposed to strengthen BWC institutions?

11. The most extensive effort to strengthen the BWC took place from 1992 to 2001 in the effort to develop verification and other measures in a draft protocol to the Convention. In 1992 and 1993, the States Parties conducted an examination of possible verification measures to enhance or assess compliance with the Convention in the Ad Hoc Group of Governmental Experts ("VEREX"). Participants examined seven broad categories of measures: information monitoring, data exchange, remote sensing, on-site inspections, off-site inspections, exchange visits, and continuous monitoring. In the end, the Group determined that the measures evaluated "could be useful to varying degrees in enhancing confidence, through increased transparency," that "reliance could not be placed on any

single measure," and that "some measures in combination could provide enhanced capabilities…thereby improving the possibility of differentiating between prohibited and permitted activities and of resolving ambiguities about compliance." This carefully-worded conclusion sufficed to paper over significant differences of view among States Parties about what was and was not possible.

12. In 1994, a Special Conference considered the results of VEREX. It decided, "to consider appropriate measures including possible verification measures, and draft proposals to strengthen the Convention, to be included as appropriate in a legally binding instrument to be submitted for the consideration of States Parties." While the United States believed that verifying compliance with the BWC would be very difficult and additionally could not be achieved through a multilateral, internationally managed BWC verification regime, a negotiation mandate was drafted. The United States participated in negotiations on a legally binding instrument because it supported the objectives of strengthening the convention and enhancing confidence in compliance.

13. In 2001, following seven years of negotiations, the Ad Hoc Group (AHG) Chairman produced a "Composite Text" of a legally binding instrument – a Protocol. The "Composite Text" reflected his best judgment as to what might achieve a consensus result since this was an exceptionally challenging task given the widely diverging and hotly contested views on what ought to be included in such a Protocol and the nature, extent and scope of measures to be included in it. The resulting draft Protocol contained a series of measures modeled in part on those of the Chemical Weapons Convention, including a verification or transparency structure providing for declarations, visits), and investigations (challenge inspections). In addition, there were also elements on responding to use as well as types of investigations into allegations of non-compliance. The draft Protocol set out in the composite text also addressed scientific cooperation, and contained provisions related to technical exchanges, assistance, and protection, as well as the establishment of an international organization to assist in its implementation.

Why did the United States reject the draft 2001 BWC Protocol?

14. As explained by the United States special negotiator, Ambassador Donald A. Mahley, on July 25, 2001, the United States concluded that the draft Protocol did not meet its mandated objective to strengthen confidence in compliance with the BWC. The United States judged that the draft Protocol would not improve its ability to detect noncompliance, nor would it deter those States seeking to develop biological weapons. This assessment remains valid today.

15. The United States subjected the "Composite Text" proposal to detailed scientific and technical scrutiny before concluding that the draft Protocol would put U.S. national security and confidential business information at risk. The Composite Text would not have represented the end-point of the AHG negotiating process: indeed, a number of countries that now support it actually rejected it in 2001 as a basis for further work, instead calling for negotiations to proceed on the basis of the "rolling text" that preceded it – a document containing approximately 1,400 brackets.

16. The United States recognizes that there is no such thing as 100 per cent verification. The purpose of verification measures is to provide assurance that others are abiding by their core treaty commitments. Effective measures should provide a powerful disincentive against cheating, due to the risk of detection and corresponding consequences. If verification measures are successful, such assurance should reduce others' motivations to hedge or cheat and may reduce the need for investment in defensive measures. The United States seeks, however, to ensure that agreements we enter into are "effectively verifiable." That does not mean that there is, or ever can be, certainty that a violation will be detected.

Rather, the United States seeks to achieve reasonable confidence - under the circumstances - that detection of significant noncompliance will occur in time to take an appropriate response. Effective verification, however, also includes detection of patterns of marginal violations. While some States Parties may be willing to accept a package of measures that would not provide this level of confidence, the limited benefits of such a regime must be weighed against the costs and risks posed by the proposed regime.

17. The central objective of a compliance monitoring regime is to uncover illicit activity. A related objective would be to deter or complicate the ability of a rogue state to conduct an illicit biological weapons program. Another objective would be to agree on a declaration base that would provide reasonable inventories to reflect the scale of activity relevant to the BWC. The United States concluded after careful examination of the measures in the draft Protocol that none of these objectives would be met.

18. In particular, the United States does not consider that a combination of international data declarations, related confidence-building measures, and on- or off-site inspection regimes are sufficient for reliably detecting significant noncompliance with the BWC. The key problems are as follows:

- Defining what facilities are relevant: Given the small size and inherently dual-use nature of many biological facilities, the United States does not believe it is possible to develop and agree on criteria that reliably identify facilities that are "BW capable" and distinguish them from other biological facilities. The draft protocol focused on an incomplete and relatively arbitrary subset and ignored other facilities that may be equally capable. Schemes such as the U.S. "Federal Select Agent Program" aim to regulate work with specific pathogens; however, a government seeking to pursue a clandestine BW effort could readily conceal small stocks of pathogens for use at an undisclosed facility – or could conduct weapons development work or even maintain bulk agent production capabilities in plain sight under a cover story.

- Lack of clear indicators: Assuming a facility being used for BW purposes is declared and inspected, would there be signatures that would clearly indicate potential noncompliance? Under certain limited circumstances, there might be such indicators – for example, orders of growth medium inconsistent with stated purpose, filling lines and munitions – but most potential "indicators" could have legitimate peaceful applications and be readily explainable. It is sometimes suggested that an astute inspector may be able to spot a compliance issue even without clear, specific indicators that lack credible alternative explanations. Under such circumstances, though, it could be difficult to persuade States Parties to address an issue in the absence of clear evidence.

- Ambiguous or missing indicators of illicit activity work both ways: in addition to the possibility of false negatives, in which treaty violations go undetected, they can also lead to false positives, in which fully compliant activities (for example, technical work conducted for public health, pharmaceutical research, fundamental science, or biodefense objectives) can appear to be illicit.

- Without the ability of an international regime to reliably detect noncompliance, such a framework therefore increases the risk that violators would point to the verification/inspection regime's lack of any findings to the contrary and claim they are fully compliant, thereby eroding international will to address concerns, as well as the risk that compliant parties may appear to be treaty violators. Either outcome would be highly corrosive to a compliance regime.

19. The United States recognizes that declarations, site visits, and other measures can provide useful and sometimes invaluable information. Such information, combined with

national means, may allow individual States Parties to draw conclusions about compliance and have obvious utility for confidence building, but we are not aware of any combination of multilateral measures that could definitively confirm compliance with the BWC in a meaningful sense.

Are there ways to make the Biological and Toxin Weapons Convention effectively verifiable through an international verification regime?

20. As indicated above, the United States does not know of any formal mechanism or set of agreed procedures that would enable Parties to verify that core prohibitions as set out in Articles I and II of the BWC are being met. When biological weapons are not stored in quantity or actually employed, the ability to distinguish the prohibited from permissible (i.e. verification), often hinges on intent. Making a judgment about intent is, difficult, given the dual-use nature of most biotechnology equipment, facilities, and activities, but it all depends on the National Technical Means.

What measures have been adopted to strengthen the BWC regime?

Confidence-Building Measures:

21. Almost from the day the BWC entered into force, its implementation and effectiveness have been strengthened in a number of ways. The Confidence-Building Measures (CBMs) count among these efforts. At the very first BWC Review Conference in 1980, State Parties were encouraged to submit voluntary declarations on three issues: (1) past and/or present possession of items prohibited under the BWC (i.e., agents, toxins, weapons, equipment or means of delivery as specified in Article I of the Convention); (2) destruction and/or diversion to peaceful uses of any such items; and (3) national legislation to support the Convention. At the second BWC Review Conference in 1986, Parties expanded politically binding submissions to include exchanging information on research centers and labs that work with high risk biological materials or specialize in permitted biological activities directly related to the Convention, and abnormal outbreaks of infectious diseases. They also agreed to encourage publication of results of biological research directly related to the Convention and to promote contacts among scientists engaged in such research. An ad hoc meeting of scientific and technical experts met in 1987 to finalize ways and means for exchange of this information. This annual politically binding information exchange, or "Confidence-Building Measures," aimed to "prevent or reduce the occurrence of ambiguities, doubts and suspicions."

22. These CBMs have been subsequently elaborated, in stages, including at the Third, Sixth, and Seventh Review Conferences, and now include requests for more detailed information. In addition, in order to encourage greater participation in the CBMs, the formats have been simplified, and step-by-step guidance on how to prepare CBMs is available. The BWC's Implementation Support Unit is also working on an electronic submission form, per requests of previous Review Conferences. States Parties can choose whether to post their CBMs on the public website of the BWC or on a confidential site only available to other Parties. As indicated by the topics for intersessional discussion of national implementation during the Meetings of BWC Experts in 2018-2020, CBMs will once again be addressed in terms of quantity and quality, and merit consideration not only in connection with national implementation, but also in the context of institutional strengthening of the Convention.

Article V:

23. Efforts have been made to elaborate and strengthen procedures related to implementation of Article V on consultation and cooperation, especially at the Second and Third BWC Review Conferences, including specifying how a formal consultative meeting of the States Parties could be convened and conducted. These provisions were designed to encourage States Parties with concerns about compliance and implementation to use the mechanisms available in the Convention to address those concerns. Some States Parties have raised such issues bilaterally or trilaterally, using a variety of approaches consistent with Article V. The mechanism for a formal consultative meeting of the States Parties was used only once, in 1997, when Cuba called for Formal Consultative Meeting to consider its groundless allegations against the United States (the United States was wrongly accused of purposefully attacking Cuban agriculture by releasing an insect pest over its fields). The Consultative meeting convened and the issues raised by Cuba were considered. Following review of subsequent information, consultations and meetings with the Vice-Chairmen, the Chair of the Formal Consultative Meeting, UK Ambassador to the CD Ian Soutar, reported in a letter to States Parties that it was not possible to reach a definitive conclusion. He also reported that the meeting was a success insofar as it demonstrated that States Parties could come together using the procedures developed to implement Article V and provide a forum for States Parties to present information relevant to the concerns that had been voiced. The United States delegation, among others, sought further understandings associated with implementation of Articles V and VI to render them more "user friendly" and effective, and looks forward to discussing these proposals during these intersessional considerations of approaches and further options to strengthen the Convention.

Intersessional Process:

24. The intersessional process (ISP) itself, first established at the resumed meeting of the Fifth BWC Review Conference in 2002 to discuss and promote common understanding and effective action on a number of practical items, has registered a series of successes. Subsequent ISPs have succeeded in a number of areas by laying the groundwork for individual States Parties to take specific, concrete action aimed at strengthening the BWC and its implementation. Important among the issues addressed have been those focused on the need to enhance practices relating to the handling of, access to, and thus security of, dangerous pathogens, including biosafety/biosecurity standards. BWC ISP discussions encouraged Parties to take steps to enhance biosafety and biosecurity, and a number subsequently have done so. The ISP focus on enhancing awareness of the BWC, and encouraging responsible behavior by life scientists, including oversight, education and codes of conduct, has also led to a number of concrete actions, including the 2005 statement by the Interacademy Panel (IAP) on biosecurity, which contains guidance for developing codes of conduct and was supported by 68 national academies of science. A number of other entities produced new, or embellished existing, codes of conduct/ethics to address bio-risks, including the American Society for Microbiology (ASM), the Royal Society in the United Kingdom, the Royal Netherlands Academy of Arts and Sciences, and the Chinese Academy of Sciences (CAS). Other measures arising from ISP focus included establishing national measures to implement the BWC, including legislation; enhancing capabilities for responding to, investigating, and mitigating the effects of suspicious outbreaks of disease and/or allegations of use; and strengthening disease surveillance.

Implementation Support Unit:

25. The Implementation Support Unit (ISU) was established at the Sixth Review Conference to provide administrative support to States Parties. The ISU's mandate was renewed and supplemented at the Seventh Review Conference, and again renewed at the Eighth Review Conference. The ISU now also performs a number of other tasks, including

supporting and assisting national implementation and CBMs, encouraging universality, and assisting efforts of Parties to implement Review Conference decisions and recommendations. The ISU maintains the Assistance and Cooperation Database; facilitates exchanges of information among Parties; manages the sponsorship program; and has developed a variety of online tools of use to Parties. The scope of the ISU's work has broadened significantly over the years, but its staff has not expanded in kind. Although the ISU has capably done "more with less," the United States proposes that it be expanded to better serve the interests of the Parties and strengthen the BWC.

International Cooperation and Assistance Efforts:

26. Finally, efforts to enhance international cooperation and assistance regarding BWC implementation have also strengthened the BWC. In 2011, the Seventh Review Conference established a "database to facilitate the exchange of requests for, and offers to provide, assistance and cooperation among States Parties," which was continued by decision of last December's Meeting of States Parties. Maintained by the ISU, the database contains information on both requests and offers for assistance, strengthening the implementation of Article X in particular. A new interactive database was introduced by the ISU at the December 2017 MSP. Options to enhance the cooperation database are among the issues we seek to address during the upcoming meeting of experts.

27. In addition to the measures agreed specifically by the BWC States Parties, a number of other international mechanisms, instruments, and initiatives have strengthened international security against use of biological weapons and thus serve to strengthen the BWC regime. Among these are the UN Secretary-General's Mechanism for investigating alleged biological weapons attacks (UNSGM), the International Convention for the Suppression of Terrorist Bombings, UN Security Council Resolution 1540, the International Health Regulations, and the Global Health Security Agenda and Global Partnership. Together these mechanisms, instruments, and initiatives comprise a broad international framework against biological weapons.

What measures would be useful in building confidence in BWC compliance?

28. As it explained at the 2017 Meeting of States Parties, the United States considers that there are a number of steps States can take to "further strengthen, the Convention and its functioning through possible additional legal measures or other measures in the framework of the Convention." Such steps include, but are not limited to:

- Setting the BWC on a firm financial and organizational foundation, including supporting and expanding, as appropriate, the Implementation Support Unit, and developing financial measures that provide stability and support for BWC implementation;
- Promulgating, implementing, and strengthening national implementation measures, [including rule of law and export control];
- Establishing national focal points, and ideally, a national authority;
- Encouraging enhanced transparency and confidence-building, including through improvements in the process and content of CBMs;
- Achieving universal membership in the Convention;
- Further developing the consultation and compliance resolution processes of BWC Articles V and VI (see proposals made at the Eighth Review Conference, including those of the United States);

- Developing understandings and capacities associated with assisting any State Party that has been subject to use of BW, consistent with Article VII; and
- Clarifying the important role of the UNSGM, and enhancing the SG's abilities to use said mechanism.

A possible way ahead for discussions on institutional strengthening of the BWC

29. Developments since 1975, and particularly since 2001, make clear that verification, as traditionally understood and practiced in arms control by the United States, is not very applicable to the BWC in the 21st century. A new process should commence taking those developments into account and producing results prior to the 2021 BWC Review Conference. The United States believes that it would be useful for the Experts Group on Institutional Strengthening, at the beginning of its three-year work effort, to address the following questions:

- What specific objectives are we seeking to accomplish through measures for institutional strengthening?
- How can we most readily meet those objectives? What specific measures would we need?
- How can efforts not initiated by BWC Parties, but that serve the same general objectives as the Convention, be more closely linked to the BWC?
- How can we strengthen BWC implementation to address the non-State actor threat?

30. How can we strengthen the BWC regime to take account of the scientific and technical developments characterized above, including by ensuring responsible conduct of those using biological agents and biotechnologies?